K073143



APR - 7 2008

## 5.0 510(k) SUMMARY

In accordance with Title 21 Code of Federal Regulations (21 CFR), Part 807, and in particular, §807.92, the following 510(k) summary is provided for the *Modified VertiFlex® Spinal Screw System*:

### 5.1 Submitted By:

VertiFlex®, Incorporated
1351 Calle Avanzado
San Clemente, California 92673
Contact: Steve Reitzler, Vice President of Regulatory & Quality Assurance

Date Prepared: November 2, 2007

### 5.2 Device Name

| | |
|---|---|
| Trade or Proprietary Name: | *Modified VertiFlex® Spinal Screw System* |
| Common or Usual Name: | Pedicle Screw System |
| Classification Name: | Pedicle Screw Spinal System |
| Classification Regulation: | 21 CFR, §888.3070 |
| Product Codes: | MNH, MNI, NKB |

### 5.3 Predicate Devices

The subject device is substantially equivalent, in whole or in part, to the following commercially available predicate device:

*VertiFlex® Spinal Screw System* – (VertiFlex®, Inc.; K062670)
*Isobar® TTL System* – (Scient'x; K991326, et seq)
*Dynesys™ System* – (Zimmer Spine; K031511, et seq)
*N Fix II (N Flex) System* – (N Spine; K061774)
*CD HORIZON® System* – (Medtronic; K063670 & K060615)
*AccuFlex™ (Protex™) System* – (Globus Medical; K0520690
*ZODIAC® DYNAMO™ System* – Alphatec; K072081)

### 5.4 Device Description

The *Modified VertiFlex® Spinal Screw System* is, like the predicate *VertiFlex® Spinal Screw System*, a posterior, non-cervical instrumentation system consisting of both pedicle screws and connecting rods. Screws are of polyaxial or monoaxial (fixed) top-loading design, are composed of titanium alloy conforming to ASTM F136-02, and are available in a range of diameters and lengths to accommodate anatomical requirements. Rods are available in rigid or semi-rigid forms, and are composed of titanium conforming to ASTM F67-06, or titanium alloy (Ti 6Al-4V) conforming to ASTM F136-02. Rods are available in both straight and curved styles, and in a range of lengths to accommodate both single-level and multi-level procedures. The *Modified VertiFlex® Spinal Screw System* may be implanted by either conventional surgical methods, or using minimally-invasive/percutaneous techniques. Manual instrumentation for implantation of the *Modified VertiFlex® Spinal Screw System* is available for both conventional and minimally-invasive procedures. Screws, rods, and instruments are offered non-sterile, and are intended to be sterilized by the user before use.

## 5.5 Intended Use

*When used as a pedicle screw fixation system in skeletally mature patients, the* Modified VertiFlex® Spinal Screw System *is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar, and sacral spine: Degenerative spondylolisthesis with objective evidence of neurological impairment, kyphosis, and failed previous fusion (pseudoarthrosis).*

*In addition, when used as a pedicle screw fixation system, the* Modified VertiFlex® Spinal Screw System *is indicated in patients who are receiving fusions with autogenous graft, who are having the device fixed or attached to the lumbar or sacral spine, and who are having the device removed after the development of a solid fusion mass.*

## 5.6 Comparison to Predicate Devices

Testing and comparisons of design characteristics and features have established that the subject *Modified VertiFlex® Spinal Screw System* is substantially equivalent in design, materials of composition, indications, performance, and other features, to other commercially-available predicate pedicle screw systems having semi-rigid rods.

## 5.7 Summary of Non-Clinical Tests

Non-clinical tests, including biomechanical studies, and those conducted in accordance with such recognized standards as ASTM F1717, *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*, have demonstrated the substantial equivalence of the subject device to commercially-available predicate devices in terms of performance.

## 5.8 Summary of Clinical Tests

No clinical testing was conducted to support this submission.

## 5.9 Conclusions

The results of testing and comparisons have established the substantial equivalence of the subject device to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2008

VertiFlex™, Inc.
% Mr. Steve Reitzler
VP, Regulatory and Quality
Assurance
1351 Calle Avandazo
San Clemente, California 92673

Re: K073143
Trade/Device Name: Modified VertiFlex™ Spinal Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: NKB, MNI, MNH
Dated: March 24, 2008
Received: March 27, 2008

Dear Mr. Reitzler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for the indication of spinal stabilization without fusion have not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K073143

Device Name: *Modified VertiFlex™ Spinal Screw System*

Indications for Use:

*When used as a pedicle screw fixation system in skeletally mature patients, the* Modified VertiFlex® Spinal Screw System *is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar, and sacral spine: Degenerative spondylolisthesis with objective evidence of neurological impairment, kyphosis, and failed previous fusion (pseudoarthrosis).*

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Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for MXM

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K073143